IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC., Plaintiff, v. ACCORD HEALTHCARE, INC., Defendant.	C.A. No. 18-956 (MSG)

DECLARATION OF DR. ROBERT O. WILLIAMS III

I. Introduction

1. I, Dr. Robert O. Williams III, have been retained as an expert witness in this case on behalf of the plaintiff, Amgen Inc.

2. I understand that the Defendant in this case submitted an abbreviated new drug application to the FDA seeking approval to market generic versions of Amgen's Senispar® (cinacalcet HCl) product. I understand that Amgen sued Defendants for infringement of U.S. Patent No. 9,375,405 ("the '405 patent," Rothman Decl. Ex. 1.)

3. The '405 patent claims cover pharmaceutical compositions comprising cinacalcet HCl and pharmaceutically acceptable excipients for the treatment of hyperparathyroidism, hyperphosphonia, hypercalcemia, and elevated calcium phosphorus product.

4. I have been asked to provide my opinions regarding certain scientific issues concerning the pharmaceutical compositions claimed in the '405 Patent, which I understand may be relevant to the Court's interpretation of the '405 Patent claims.

II. Qualifications

5. My educational background, professional activities, and qualifications as an expert in pharmaceutical formulation are set forth in my curriculum vitae, which is attached as Exhibit A. If called upon to testify, I may testify about any of the qualifications described in my curriculum vitae. I have also set forth selected relevant experience in the paragraphs that follow.

6. I received a B.S. in Biology with special honors from Texas A&M University in 1979. I then received a B.S. in Pharmacy with special honors from the University of Texas at Austin in 1981 and a Ph.D. in pharmaceutics from the University of Texas at Austin in 1986.

7. I am currently Professor of Pharmaceutics, Johnson & Johnson Centennial Chair, College of Pharmacy at the University of Texas at Austin. I have been a professor of pharmaceutics since 1995. I have taught courses in pharmaceutics, advanced product

development, and advanced pharmaceutical processing, among others. I am also the division head of the Division of Molecular Pharmaceutics and Drug Delivery at the University of Texas at Austin, a position I have held since 2007. Broadly speaking, pharmaceutics is the science of formulating and characterizing a pharmaceutical dosage form to deliver a drug to a human being.

8. I supervise a laboratory conducting research in various areas related to pharmaceutical formulation, including novel drug delivery systems and modified release oral dosage forms. During my time as a professor, I have supervised the research of 58 Ph.D. candidates, visiting scientists, and post-doctoral fellows.

9. Prior to and during my time as a professor, I have worked for several different companies in the field of pharmaceutical formulation, including as a Group Leader at Eli Lilly and Company, and a Section Manager, Department Manager, and Director at Rhone-Poulenc Rorer. I founded PharmaForm LLC, a company that provided product development and manufacturing services. I also founded and served as chief scientist of Enavail LLC, a company that provided particle engineering solutions to the pharmaceutical industry.

10. I have authored over 450 publications in peer-reviewed scientific journals, abstracts, and book chapters concerning pharmaceutical formulation. I have also co-edited three books concerning pharmaceutical drug delivery technology.

11. In addition, I am an inventor of over 35 patents and patent applications concerning pharmaceutical formulation.

12. A list of the matters in which I have testified as an expert at trial or at deposition in the past four years is attached as Exhibit B. A list of the materials I considered in forming my opinions in this case is attached as Exhibit C.

III. Person of Ordinary Skill in the Art

13. For purposes of my analysis in this case, I was instructed to consider the questions posed to me from the perspective of a person of ordinary skill in the art ("POSA") at the time the '405 patent application was filed in 2003 and when the Examiner's Amendment issued on March 25, 2015.

14. The '405 patent concerns the art of pharmaceutics or pharmaceutical formulation. A pharmaceutical formulator combines substances, including one or more therapeutically active ingredients and (in most cases) one or more inactive ingredients, to create a pharmaceutical composition to deliver the therapeutically active ingredient to a human being.

15. In my opinion, a POSA would have had a Ph.D. in pharmacy, chemistry, or a related discipline, and at least two years of practical experience in the field of pharmaceutical formulation. Alternatively, a POSA could have had a lesser degree in one of these disciplines if he or she had at least four years of practical experience in the field of pharmaceutical formulation. In addition, to arrive at the invention of the '405 patent, a POSA would have also had to consider the selection of a particular salt form of a particular compound, namely a hydrochloride salt of cinacalcet, as an active ingredient in a pharmaceutical composition for the treatment of hyperparathyroidism, hyperphosphonia, hypercalcemia, and elevated calcium phosphorus product. (*See, e.g.*, '405 Patent, Rothman Decl. Ex. 1, claim 1.) Therefore, it is my opinion that the POSA would have also had access to information concerning and/or individuals possessing knowledge and skills in the fields of drug discovery, salt selection, and treatment of hyperparathyroidism, hyperphosphonia, hypercalcemia, and elevated calcium phosphorus product. Such individuals would have included medicinal chemists, nephrologists, oncologists, and other medical doctors.

IV. The Binders Listed in Element (c) of Claims 1 and 20 Have Binding Attributes in Common

16. Element (c) of claims 1 and 20 reads as follows: "from about 1% to about 5% by weight of at least one binder selected from the group consisting of povidone, hydroxypropyl methylcellulose, hydroxypropyl cellulose, sodium carboxymethylcellulose, and mixtures thereof."

17. I was asked to consider, from the perspective of a POSA, whether the excipients listed in claim 1 element (c)—povidone, hydroxypropyl methylcellulose ("HPMC"), hydroxypropyl cellulose ("HPC"), sodium carboxymethylcellulose ("SCMC")—had any attributes in common.

18. A POSA would have known that orally administered tablets could be formulated using wet techniques, such as wet granulation and spheronization, which are noted in the '405 patent. ('405 patent, Rothman Decl. Ex. 1, col. 9, ll. 42-45.)

19. For example, to create a tablet, powdered ingredients are compressed into the shape of tablet. Very fine powders may not be sufficiently compressible for tableting, and in such cases the powders must be granulated. Granulation is the process of agglomerating these fine particles into larger "granules."

20. Wet granulation is one of the most common granulation techniques, and involves adding a liquid solution to powders. In wet granulation, granules are formed by adding a liquid called a "granulation liquid" or "granulating fluid" to the powder while the powder is agitated by an impeller, fluidized air, or other means. The agitation and wetting of the powdered components causes the powder to agglomerate into larger "granules."

21. A POSA would have known that granules can be formed by wet processing (massing) techniques, such as wet granulation, which involve the massing of a mix of dry

primary powder particles using a granulating fluid. (Aulton, Rothman Decl. Ex. 2, at 366.) The granulating fluid is usually used as a solvent containing a dissolved adhesive known as a binder. (*Id.*) A POSA would also know that such techniques may require experimentation to achieve a desired result.

22. A POSA would have known that povidone, HPMC, HPC, and SCMC can all function as binders in pharmaceutical formulations prepared using wet processing (massing) techniques. (Handbook of Pharmaceutical Excipients, Rothman Decl. Ex. 3, at 317-322, 326-329, 581-585, 118-121.)

23. A POSA would have further understood that povidone, and the cellulose derivatives HPMC, HPC, and SCMC have binding attributes in common when used in tablets formed by wet processing (massing) techniques. (Aulton, Rothman Decl. Ex. 2, at 368.)

24. A POSA would have known that one type of binder that can be used in wet processing (massing) techniques is a hardening binder. Hardening binders function by forming liquid bridges between particles, and then the adhesive hardens or crystallizes on drying to form solid bridges to bind the particles together as the solvent is removed. (Aulton, Rothman Decl. Ex. 2 at 368).

25. Povidone, HPMC, HPC, and SCMC all function as hardening binders. These binders can be included in the granulating solvent or the solvent can be used to mass the powder containing these binders. In either case, a POSA would have known that these hardening binders all function by forming liquid bridges between particles, and the adhesive will harden or crystallize on drying to form solid bridges to bind the particles as the solvent is removed. (Aulton, Rothman Decl. Ex. 2 at 368).

V. Many Pharmaceutical Excipients Are Multi-Functional

26. I was also asked to consider whether a POSA would have understood that the excipients (inactive ingredients) listed in claims 1 and 20 of the '405 patent can be multi-functional.

27. It is my opinion that a POSA would have known that certain inactive ingredients typically used in oral pharmaceutical formulations, including some of those listed in claims 1 and 20, can have multiple functions.

28. For example, in the Examples provided in the '405 patent, one of the ingredients is pregelatinized starch, which is categorized as a diluent in claim 1. Pertinent text from column 11 of the '405 patent is provided below:

Three pharmaceutical formulations with target amounts of 30 mg, 60 mg, and 90 mg active pharmaceutical ingredient with the following components were prepared:

	Weight % (w/w)	30 mg Tablet Amount (mg)	60 mg Tablet Amount (mg)	90 mg Tablet Amount (mg)
Cinacalcet HCl	18.367	33.06	66.12	99.18
Pregelatinized starch (Starch 1500)	33.378	60.08	120.16	180.24
Microcrystalline cellulose (Avicel PH102)	6.678	12.02	24.04	36.06
Povidone (Plasdone K29/32)	2.044	3.68	7.36	11.04
Crospovidone (Polyplasdone XL)	1.233	2.22	4.44	6.66
Purified Water[1]	—	—	—	—
Microcrystalline cellulose (Avicel PH102)	34.300	61.74	123.48	185.22
Magnesium stearate	0.500	0.90	1.80	2.70
Colloidal silicon dioxide (Colloidal anhydrous silica) (Cab-O-Sil M5P)	0.500	0.90	1.80	2.70
Crospovidone (Polyplasdone XL)	3.000	5.40	10.80	16.20
Core Tablet	100.000	180.00	360.00	540.00
Purified Water[1]	—	—	—	—
Opadry ® II (colored film former)	4.000	7.20	14.40	21.60
Purified Water[1]	—	—	—	—
Opadry ® Clear (clear film former)	1.500	2.70	5.40	8.10
Carnauba Wax Powder	0.010	0.018	0.036	0.054
Opacode ® Ink (Black)[2] 1	—	—	—	—

[1]The purified Water was removed during processing.
[2]Trace quantities of ink were applied to the coated tablet.

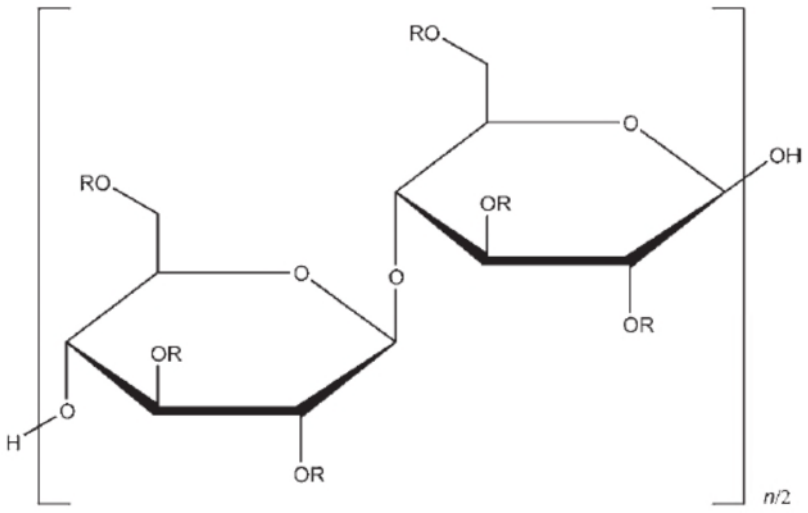
29. A POSA would have known, however, that pregelatinized starch can have multiple functions. In addition to functioning as a diluent in a particular formulation it can, for example, also exhibit binding and disintegrating characteristics. A POSA also would have known that pregelatinized starch may exhibit these multiple functions in the same formulation. (Handbook of Pharmaceutical Excipients, Rothman Decl. Ex. 3, at 691-694).

30. The same is true, for example, of microcrystalline cellulose, which is included in the Example and is categorized as a diluent in claims 1 and 20. (Handbook of Pharmaceutical Excipients, Rothman Decl. Ex. 3, at 129-133.)

VI. Hydroxypropyl Methylcellulose

31. Hydroxypropyl methylcellulose ("HPMC"), also known as hypromellose, is a cellulose hydroxypropyl methyl ether, available in grades containing 16.5% to 30.0% of methoxy and 4.0 to 32.0% of hydroxypropoxy groups. (Remington, Rothman Decl. Ex. 4, at 1032; Handbook of Pharmaceutical Excipients, Rothman Decl. Ex. 3, at 326-329).

32. HPMC is a polymer that has the structural formula depicted below:



where R is H, CH_3, or $CH_3CH(OH)CH_2$

(Handbook of Pharmaceutical Excipients, Rothman Decl. Ex. 3, at 326).

33. A POSA would have known that HPMC is available as both a standalone product consisting of about 100% HPMC, and as products such as "Opadry Green," in which HPMC is pre-mixed with other ingredients. These products contain HPMC and additional ingredients.

34. Chemically, there is no difference between the HPMC in a standalone product and the HPMC in a premixed product such as Opadry Green. The HPMC in premixed products is the same chemical substance as is contained in standalone HPMC products.

35. A POSA would have understood that "hydroxypropyl methylcellulose" refers to any hydroxypropyl methylcellulose present in a pharmaceutical formulation, regardless of how it was added to the formulation, i.e., regardless of whether it was premixed with other substances before being added to the formulation or not.

Dated: 6/28/2019

Robert O. Williams III

Robert O. Williams III

EXHIBIT A

CURRICULUM VITAE
Robert O. (Bill) Williams III

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The University of Texas at Austin
College of Pharmacy
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Publications: see,
http://www.ncbi.nlm.nih.gov/sites/myncbi/1hUAjikknhsQ8/bibliography/48270711/public/?sort=date&direction=ascending
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(512) 306-8396

I. Personal

Born September 11, 1956 in Beaumont, Texas. Citizen of the United States. Married; two children.

II. Education

May 75 – May 79	Texas A&M University, College Station, Texas Bachelor of Science in Biology, Graduated with special honors
Sep 79 – Dec 81	University of Texas at Austin, Austin, Texas. Bachelor of Science in Pharmacy, Graduated with special honors Registered Pharmacist – State of Texas
Aug 82 – May 86	University of Texas at Austin, Austin, Texas Doctor of Philosophy, Pharmaceutics Major Professor: James W. McGinity, Ph.D.

III. Positions Held

1. January, 1982 to August, 1982 – Registered, Pharmacist, Walgreen's Pharmacy, Beaumont, TX.
2. August, 1986 to December, 1988 - Group Leader for Eli Lilly and Company, Indianapolis, IN.

3. January, 1989 to December, 1990 - Director for Duramed Pharmaceuticals, Cincinnati, OH.
4. January, 1991 to April, 1992 - Section Manager for Rhone-Poulenc Rorer Pharmaceuticals, Collegeville, PA.
5. April, 1992 to January, 1993 - Department Manager for Rhone-Poulenc Rorer Pharmaceuticals, Collegeville, PA.
6. January, 1993 to August, 1995 - Director for Rhone-Poulenc Rorer Pharmaceuticals, Collegeville, PA.
7. September, 1995 to August, 1999 - Assistant Professor of Pharmaceutics, College of Pharmacy, University of Texas at Austin, Austin, TX.
8. January, 1996 to January, 2007 – President, PharmaForm LLC, Austin, TX.
9. January, 2007 – June, 2010 – Consultant, PharmaForm LLC, Austin, TX.
10. January, 2007 to June, 2010 – Board of Directors, Akela Pharma, Inc., Montreal, Canada
11. September, 1999 to August, 2004 – Associate Professor of Pharmaceutics, College of Pharmacy, University of Texas at Austin, Austin, TX.
12. September, 2004 to 2013 – Professor of Pharmaceutics, Johnson & Johnson Centennial Professor, College of Pharmacy, University of Texas at Austin, Austin, TX.
13. September, 2007 to present – Division Head, Division of Pharmaceutics, College of Pharmacy, University of Texas at Austin, Austin, TX.
14. 2009-2013, Founder and Chief Scientist, Enavail LLC, Austin, TX.
15. January, 2013 to present – Visiting Professor, University of Chile, Santiago, Chile.
16. September, 2013 to present – Professor of Pharmaceutics, Johnson & Johnson Centennial Chair, College of Pharmacy, University of Texas at Austin, Austin, TX.

IV. Graduate and Undergraduate Courses Presented

Pharmaceutics, PHR 356C and PHR 156P - UT Austin
Advanced Manufacturing Pharmacy, PGS 381G - UT Austin
Recent Advances in Pharmaceutics, PGS 382R - UT Austin
Advanced Product Development, PGS 381D - UT Austin
Advanced Pharmaceutical Processing, PGS 380Q - UT Austin
Pharmaceutical Entrepreneurship, PHR 261J/PGS 280M – UT Austin

V. Professional Memberships

American Association of Pharmaceutical Scientists 1985 - present
(Sections of Pharmaceutical Technology, and Pharmaceutics and Drug Delivery)
- Member, Planning Committee, Pharmaceutical Technology Section (1997-1998)
- Member, Strategic Planning Committee (1999-2000)
- Reviewer, Pharmaceutical Technology Screening Committee (2003, 2004)
- Co-Chair, Strategic Visioning Process (2003-2004)

Reviewer, Annual Meeting and Exposition Abstract Screening Committee (2006)
Member, Pharmaceutical Technology Education Committee (2007)

Controlled Release Society	1995 - present
Association de Pharmacie Galenique Industrielle (APGI)	1998 - present
American Association of Colleges of Pharmacy	1995 - present
Rho Chi (Pharmacy Honor Society)	1982 - present
Kappa Psi (Graduate Chapter, Pharmacy Professional Fraternity),	1979 - present
Grand Council Deputy - President	1998 – present
International Academy of Compounding	1999 – 2004
European Federation of Biotechnology	2002 – 2013
Product Quality Research Institute (AAPS representative on Drug Product Technical Committee)	2004 – 2005
Center for Microencapsulation and Drug Delivery, Texas A&M University (Member – Strategic Advisory Board)	2003-2013
Austin Technology Incubator University Development Portfolio, Member	2014-present
National Institute for Pharmaceutical Technology and Education Chair, NIPTE Faculty Committee – 2017-2019	2015-present

VI. Current Research Interests

1. Small particle technology to enhance dissolution rates and bioavailability.

2. Formulation of novel liquid and semisolid drug delivery systems.

3. Study of novel controlled-release aqueous coating formulations.

4. Preformulation and formulation of novel delivery systems for pulmonary, nasal and buccal delivery.

5. Modified release oral dosage forms.

VII. Honors and Awards

1. University Undergraduate Honors Fellow, Texas A&M University; 1978

2. Distinguished Student Award, Texas A&M University; 1979

3. Lemmon Award, University of Texas at Austin; 1981

4. Amaric Corporation Pre-doctoral Fellowship, University of Texas at Austin; 1983 - 1985

5. Professional Development Award, University of Texas at Austin; 1985

6. Texas Excellence Teaching Award, University of Texas at Austin; 1998

7. Phi Lambda Sigma, the Pharmacy Leadership Society, Elected member - 1998

8. Leadership Fellow, American Association of Colleges of Pharmacy Academic Leadership Fellows Program, 2004-2005.

9. Paper awarded the Penwest Award for Best Scientific Paper, Novel Curing Process for Cellulose Acetate Phthalate Coated Beads. Proceedings of the 20th Pharmaceutical Technology Conference and Exhibition, Liverpool, UK, April, 2001.

10. Dean's Fellow, College of Pharmacy, University of Texas at Austin, 2004-2005.

11. Paper awarded the Controlled Release Society's Innovative Aspects of Oral Drug Delivery and Absorption Graduate/Post-Doc Award, Improved Dissolution Rate and Bioavailability Through the Formation of a Highly Miscible Binary Mixture, Proceedings of the Controlled Release Society Annual Meeting, Miami, FL, June, 2005.

12. Paper nominated for the Controlled Release Society's Innovative Aspects of Oral Drug Delivery and Absorption Graduate/Post-Doc Award, Rapid Release, High Potency Itraconazole Formed by Evaporative Precipitation Into Aqueous Solution, Proceedings of the Controlled Release Society Annual Meeting, Miami, FL, June, 2005.

13. Outstanding Thesis Award, Barbara Jean Hoeben, M.S. (May, 2005) – Thesis Title: Comparison of Commercial Itraconazole to Aerosolized Nanoparticle Itraconazole in a Murine Model for the Prevention of Invasive Pulmonary Aspergillosis (IPA).

14. Elected "Fellow" of the American Association of Pharmaceutical Scientists, 2006.

15. Elected "Fellow" of the American Institute of Medical and Biological Engineering, 2008.

16. Received the 2009 William J. Sheffield Outstanding Alumnus Award, Pharmacy Alumni Association, The University of Texas at Austin.

17. Invited paper by W. Yang, J. I. Peters and R. O. Williams III was recognized as one of the Top-10 most cited articles published in *International Journal of Pharmaceutics* during the period 2008-2010 (Elsevier Publishers; September 2010).

18. Received the Teaching Excellence Award (P1), College of Pharmacy, University of Texas at Austin, 2014-2015.

19. Received the Inventor of the Year Award, University of Texas at Austin, November 2017.

VIII. Committees

Academic Performance Committee - 1996 – present, Chairman and Member
Faculty Retreat Planning Committee, Chair - 1996-1997, 2007, 2011
Committee on Committees - 1995 – 1997, 2004 – 2005, 2006
Pharmacy Honors Course - Coordinator for Pharmaceutics - 1996 - 2001
Honors and Awards Committee - 1995 - 2001
Internship Region Assignment Committee, Chairman, 1998 - 2004
Staff Excellence Awards Committee - 1998 – 2000
Financial Aid Committee – 1999 – 2000
College Accreditation Committee – 2002 – present
Admissions and Registration Committee (University Committee) – 2001 – 2003
Intellectual Property Committee (University Committee) – 2003- 2013
Co-Chair – Life Sciences (2004-2005)
Faculty Advisor to: Kappa Psi Pharmaceutical Fraternity
Pharmaceutical Association of Compounding
Drug Product Technical Committee, PQRI – representative for AAPS, 2004-2006
Post-Tenure Review Committee – Chairman; 2005-2007
College of Pharmacy, Dean Search Committee – Co-Chairman; 2007
College of Pharmacy, Executive Committee – Chairman; 2008 – 2013
University of Texas at Austin, Office of Technology Commercialization and Associate Vice President for Research for Commercialization Search Committee; 2008-2010
Graduate Studies Committee, Pharmacy Doctoral Program (1995 – present)
Graduate Studies Committee, Translational Science Doctoral Program (2011- 2013)

IX. Editorial Responsibilities

1. *AAPS PharmSciTech* – Editor-in-Chief (2014 – present)
2. *Journal of Drug Delivery Science and Technology* – member, Editorial Advisory Board (2015-present)
3. *Pharmaceutics* - member, Editorial Advisory Board (2018-present)
4. *Drug Development and Industrial Pharmacy* – Editor-in-Chief (2000 – 2014)
5. *International Journal of Pharmaceutics* – reviewer
6. *Pharmaceutical Research* – reviewer
7. *European Journal of Pharmaceutics and Biopharmaceutics* – reviewer
8. *Journal of the Controlled Release Society* – reviewer
9. *S. T. P. Pharma. Sciences* – reviewer
10. *Pharmaceutical Development and Technology* – reviewer
11. Pharmaceutical Technology Conference - International Advisory Board Member
12. *International Journal of Pharmaceutical Compounding* – reviewer
13. *Journal of Membrane Science* – reviewer
14. *AAPS PharmSciTech* – reviewer

15. *Journal of Pharmaceutical Sciences* – reviewer
16. *Journal of Pharmaceutical and Biomedical Analysis* – reviewer
17. *Toxicology Letters* – reviewer
18. National Institutes of Health, National Institute of Allergy and Infectious Diseases, *Pharmaceutical and Chemical Resources for AIDS Drug Development*, invited reviewer.
19. *The Open Drug Delivery Journal*, Member, Editorial Advisory Board, 2008-present.
20. *Journal of Pharmaceutical Research & Clinical Practice*, Editorial Advisory Board, 2010-present.
21. *British Journal of Pharmaceutical Research*, Editorial Advisory Board, 2013-present.

X. Students Currently Being Supervised

Tamara Tarbox – Ph.D. Candidate
Xiangyu Ma – Ph.D. Candidate
Scott V. Jermain – PharmD/Ph.D. Candidate
Sawittree Sahakijpijam – Ph.D. Candidate
Daniel A. Davis – PharmD/Ph.D.
Mandy Moore – PharmD/Ph.D.
Michael Lowinger – Ph.D. Candidate
Urvi Gala – Ph.D. Candidate
Stephen A. Thompson – Pharm.D./Ph.D.
Yajie Zhang – Ph.D. Candidate

XI. Personnel Supervised (and Starting Position; if available)

1. Mongkol Sriwongjanya, Ph.D. (1996 – 1997; Post-doctoral Research Fellow) Senior Research Scientist, Andrx Pharmaceuticals, Fort Lauderdale, FL

2. Jie Liu, Ph.D. (August, 1998) Senior Research Scientist, Baxter Healthcare, New Providence, NJ. Dissertation Title: Development, Characterization and Optimization of Pressurized Metered-Dose Inhalers Formulated to Delivery Small Organic Drugs or Proteins with Hydrofluoroalkane Propellants.

3. Chengjiu Hu, Ph.D. (August, 1999) Senior Research Scientist, DuPont Pharmaceuticals, Garden City, NY. Dissertation Title: Investigation of Factors Influencing the Development of Pressurized Metered Dose Inhalers.

4. Melisa K. Barron, Ph.D. (August, 2000) Senior Scientist, Dey Laboratories, Napa, CA. Dissertation Title: Investigation of Formulation and Processing Technique on the Characteristics of Polymeric Powders Produced for Suspension Type Pressurized Metered Dose Inhalers Systems.

5. Jiping Liu, Ph.D. (August, 2001) Research Investigator, Sanofi-Synthelabo, Philadelphia, PA. Dissertation Title: Applications of Cellulose Acetate Phthalate Aqueous Dispersion (Aquacoat CPD) for Enteric Coating.

6. Bobby J. Truong, M.S. (August, 2001). Thesis Title: Development of Insulin Pressurized Meter-Dose Inhaler for the Pulmonary Drug Delivery by Spray-Freezing into Cryogenic Vapor.

7. Marazban Sarkari, Ph.D. (2000-2001; Post-doctoral Research Fellow) Senior Scientist, RxKINETIX, Boulder, CO

8. Vorapann Mahaguna, Ph.D. (December, 2001) Senior Research Scientist, DuPont Pharmaceuticals, Garden City, NY. Dissertation Title: Investigation of Cellulose Ether Polymers in Controlled Drug Delivery.

9. Raouf Ghaderi, Ph.D. (2001-2002; Post-doctoral Research Fellow) Senior Research Scientist, KOS Pharmaceuticals, NJ

10. True L. Rogers, Ph.D. (June, 2002) Senior Research Scientist, The Dow Chemical Company, Midland, MI. Dissertation Title: A Novel Cryogenic Particle Engineering Technology to Micronize Water-Insoluble Drugs and Enhance Their Dissolution Properties: Spray-Freezing Into Liquid.

11. Jiahui Hu, Ph.D. (July, 2003) – Senior Research Scientist, Forest Laboratories, Garden City, NY. Dissertation Title: A Nanoparticle Engineering Process: Spray-Freezing into Liquid to Enhance the Dissolution of Poorly Water Soluble Drugs.

12. Bradi L. Jones, Pharm.D., M.S. (August, 2003) – Pharmacist, University of Texas Health Science Center at San Antonio, San Antonio, TX. Thesis Title – Investigation of Pulmonary and Oral Delivery of Itraconazole Produced by Evaporative Precipitation into Aqueous Solution and Spray Freezing into Liquid Technology in a Murine Model.

13. Thomas W. Leach, Ph.D. (2002-2004) – Post-doctoral Research Fellow) Senior Research Scientist, Curagen Inc., New Haven, CT

14. Zhongshui Yu, Ph.D. (July, 2004) – Senior Research Scientist, Hoffmann-La Roche Pharmaceuticals, Nutley, NJ. Dissertation Title: Spray Freezing into Liquid to Produce Protein Microparticles.

15. Xiaoxia Chen, Ph.D. (July, 2004) – Senior Research Scientist, Hoffmann-La Roche Pharmaceuticals, Nutley, NJ. Dissertation Title: Nanoparticle Engineering Processes: Evaporative Precipitation into Aqueous Solution (EPAS) and Anitsolvent Precipitation to Enhance the Dissolution Rates of Poorly Water Soluble Drugs.

16. Thiago Carvoso Carvalho, R.Ph. (July, 2004) – Visiting Scientist, Universidade Federal De Minas Gerais, Brazil.

17. Barbara Jean Hoeben, M.S. (May, 2005) – Pharmacist, United States Air Force, San Antonio, TX. Thesis Title: Comparison of Commercial Itraconazole to Aerosolized Nanoparticle Itraconazole in a Murine Model for the Prevention of Invasive Pulmonary Aspergillosis (IPA).

18. Jason M. Vaughn, Ph.D. (June, 2005) – Associate Director and Senior Research Scientist, PharmaForm LLC, Austin, TX. Dissertation Title: Improved Bioavailability and Site Specific Delivery of Poorly Water Soluble Drugs through the Production of Stabilized Drug Nanoparticles.

19. Jason T. McConville, Ph.D. – (2003-2006; Post-doctoral Research Fellow) – Assistant Professor of Pharmaceutics, University of Texas at Austin, Austin, TX.

20. Prapasri Sinswat, Ph.D. (August, 2006) – Assistant Professor of Pharmaceutics, Chulalongkorn University, Bangkok, Thailand. Dissertation Title: Enhancing the Delivery of Poorly Water Soluble Drugs Using Particle Engineering Technologies.

21. Kirk A. Overhoff, Ph.D. (August, 2006) – Senior Pharmaceutical Scientist, Schering Corporation, Kenilworth, NJ. Dissertation Title: Improved Oral Bioavailability of Poorly Water Soluble Drugs Using Rapid Freezing Processes.

22. Josh D. Engstrom, Ph.D. (August, 2007) – Senior Pharmaceutical Scientist, Bristol Meyers Squibb, Princeton, NJ. Dissertation Title: Stable Submicron Protein Particles: Formation, Properties and Pulmonary Applications.

23. Keat Theng Chow, Ph.D. (2007-2008; Post-doctoral Research Fellow).

24. Masao Nagao, M.S. (2007-2008; Visiting Research Scholar) - Takeda Pharmaceuticals, Japan).

25. Dave A. Miller, Ph.D. (August, 2007) – Senior Pharmaceutical Scientist, Hoffman La Roche, Nutley, NJ. Dissertation Title: Improved Oral Absorption of Poorly Water Soluble Drugs by Advanced Solid Dispersion Systems.

26. Michal P. Matteucci, Ph.D. (August, 2007) – Dissertation Title: Highly Supersaturated Aqueous Solutions by Design of Amorphous Pharmaceutical Nanoparticles.

27. Troy P. Purvis, Ph.D. (August, 2007) – Senior Pharmaceutical Scientist, Azaya Therapeutics, San Antonio, TX. Dissertation Title: Nanoparticle Formulations of Poorly Water Soluble Drugs and their Action In Vivo and In Vitro.

28. Yosuhiro Tsutsumi, Ph.D. (2008-2009; Visiting Research Scholar) Daiichi Sankyo Co., Ltd., Pharmaceutical Technology, Japan.

29. Rui Jia, Ph. D. (2008-2009); Visiting Research Scholar; China.

30. Justin A. Tolman, Pharm.D., Ph.D. (January, 2009) – Assistant Professor of Pharmaceutics, School of Pharmacy and Health Professions, Creighton University, Omaha, Nebraska. Dissertation Title: Pulmonary Delivery of Aqueous Voriconazole Solution.

31. Alan B. Watts, Ph.D (July 2009) – Senior Scientist, Microdose Inc., Princeton, NJ, Dissertation Title: Pulmonary Delivery of Tacrolimus for Lung Transplant and Asthma Therapy.

32. Wei Yang, Ph.D. (July 2009) – Senior Scientist, Enavail, LLC, Austin, TX; Dissertation Title: Improvement of Bioavailability of Poorly Water-Soluble Drug via Pulmonary Delivery of Nanoparticles.

33. James C. DiNunzio (July 2009) – Senior Scientist, PharmaForm LLC, Austin, TX, Dissertation Title: Formulation and Processing Technologies for Enhanced Oral Bioavailability of Poorly Water Soluble Compounds.

34. Ikumasa Ohno, Ph.D. (2010-2010, Visiting Scholar) Daiichi Sankyo Co., Ltd., Pharmaceutical Technology, Japan.

35. Nicole A. Beinborn, Ph.D. (August 2011) – Senior Scientist, Aptalis, Dayton, OH; Dissertation Title: Inhaled Voriconazole Formulations for Invasive Fungal Infections in the Lungs.

36. Meimei Zhang (2009-2011) – Visiting Chinese Graduate Student Scholar, (Professor Chuanbin Wu) Department of Pharmaceutics, School of Pharmaceutical Sciences R&D Center of Pharmaceutics, Sun Yat-sen University, Guangzhou, Guangdong, China, Dissertation Title: Amorphous Fenobibrate Solid Dispersions Prepared by Thin-Film Freezing.

37. Houli Li (2009-2011) – Visiting Chinese Graduate Student Scholar, (Professor Ruichen Guo) Institute of Clinical Pharmacology, Qilu Hospital of Shandong University, Jinan, Shandong, China, Dissertation Title: Modified Release Carbamazepine Compositions Prepared by Thin-Film Freezing.

38. Kevin P. O'Donnell, Ph.D. (December 2011) – Senior Scientist, The Dow Chemical Company, Midland, MI, Dissertation Title: Pharmaceutical Technologies for Improving Drug Loading in the Formulation of Solid Dispersions.

39. Helene L. Dugas, Ph.D. (May 2012) – Territory Manager, Laboratory Sales, Wheaton Industries, Houston, TX; Dissertation Title: Mycophenolate Mofetil Inhaled Formulation for the Prevention of Lung Transplant Rejection.

40. Stephanie Bosselmann, Ph.D. (May 2012) – Senior Scientist, Berlin Chemie, Berlin, Germany, Dissertation Title: Nanoparticle Engineering for Enhanced Drug Delivery.

41. Javier O. Morales, Ph.D. (November 2012) – Assistant Professor, University of Chile, Santiago, Chile, Dissertation Title: Mucoadhesive Films for the Buccal Delivery of Insulin.

42. Shih-Fan Jang, Ph.D. (January 2013) – Dissertation Title: Development of Lower Intestine Targeting Mucoadhesive Platform of Oral Drug Delivery.

43. Bo Lang, Ph.D. (June 2013) – Formulation Scientist, Mylan Pharmaceuticals, Morgantown, WV, Dissertation Title: Advanced Formulation and Processing Technologies in the Oral Delivery of Poorly Water Soluble Drugs.

44. Yi-Bo Wang, Ph.D. (November 2013) – Reviewer, Food and Drug Administration, Division of Bioequivalence, Washington D.C., Dissertation Title: Pulmonary Delivery of Brittle Matrix Powders Produced by Thin Film Freezing.

45. Simone Raffa Carvalho, Ph.D. (November 2013) – Principal Scientist, Evonik Industries, Dissertation Title: Improved Inhalation Therapies of Brittle Powders.

46. Justin M. Keen, Ph.D. (November 2013) – Formulation Scientist, DisperSol Technologies, LLC, Austin, TX. Dissertation Title: Novel Formulations and Thermal Processes for Bioavailability Enhancement of Soluble and Poorly Soluble Drugs.

47. Ryan C. Bennett, Ph.D. (March 2014) – Pharmaceutical Scientist, Freund-Vector Corporation, Cedar Rapids, IA. Dissertation Title: Thermal Processing Cyclodextrins

and Thermoplastic Polymers for Bioavailability Enhancement of Poorly Water-Soluble Drugs.

48. Chris Brough, Ph.D. (August 2015) – Pharmaceutical Scientist, Dispersol Technologies, LLC, Georgetown, TX. Dissertation Title: Novel Uses of Pharmaceutical Polymers as Enabled by KinetiSol® Dispersing.

49. Sha Liu, Ph.D. (2013-2014, Visiting Scholar) – Assistant Professor, School of Pharmacy, Yantai University, Yantai, China. Title: Formulation of a Novel Fixed Dose Combination of Salmeterol Xinafoate and Mometasone Furoate for Inhaled Drug Delivery.

50. Yang Lu, Ph.D. (2015-2016, Visiting Scholar) – Assistant Professor, School of Chinese Material Mecica, Beijing University of Chinese Medicine, Beijing, China.

51. Leena K. Prasad, Ph.D. (July 2016) – Senior Scientist, Ironwood Pharmaceuticals, Inc., Boston, MA. Title: Electrostatic Powder Deposition as a Dry Powder Process to Prepare Orodispersible Films.

52. Justin S. LaFountaine, Ph.D. (July 2016) – Life Sciences Specialist, L. E. K. Consulting, Boston, MA. Title: Thermokinetic Processing of Supersaturating and Mucoadhesive Amorphous Solid Dispersions.

53. Masataka Hanada, Ph.D. (2016-2018, Visiting Scholar) – Research Scientist, Kyorin Pharmaceuticals, Tochigi, Japan.

54. Hiroyuki Takabe, Ph.D. (2016-2018, Visiting Scholar) – Kaken Pharmaceutical Co., Tokyo, Japan.

55. Soraya Hengsawas Surasarang, Ph.D. (September 2016) – Pharmacist, Professional Level, Department of Medical Sciences, Ministry of Public Health, Bangkok, Thailand. Title: Importance of Stability of Pharmaceutical Formulations.

56. Sophie M. Delpon De Vaux (August 2016) – Visiting Pharmacy Student Intern, Universite Paris Sud. Title: Formulation of Water Insoluble Active Drugs.

57. Siyuan Huang (January 2017) – Senior Scientist, Eli Lilly & Company, Indianapolis, IN. Title: Application of Hot-melt Extrusion in the Manufacturing of Amorphous Solid Dispersions Containing Thermally Labile Drugs.

58. Julien Maincent (August 2017) – Pharmaceutical Scientist, Vertex Pharmaceuticals, Boston, MA. Dissertation Title: Modified Release Formulations Manufactured by Hot Melt Extrusion.

59. Daniel Ellenberger (December 2017) – Pharmaceutical Scientist, DisperSol Technologies, LLC, Georgetown, TX. Dissertation Title: Processing Challenging

Active Pharmaceutical Ingredients and Polymers by KinetiSol® to Produce Amorphous Solid Dispersions with Improved IN Vitro and In Vivo Performance.

60. Zachary N. Warnken (May 2018) – Post-doctoral Fellow, The University of Texas at Austin, Austin, TX. Dissertation Title: Teaching an Old Drug New Tricks: Exploring Formulation and Route of Delivery Methods for Repurposing Drugs to Treat CNS Diseases.

61. Chaeho Moon (April 2019) – Post-doctoral Fellow, The University of Texas at Austin, Austin, TX and Senior Scientist, TFF Pharmaceuticals Inc., Austin, TX. Dissertation Title: Development of High Potency Voriconazole Nanoaggregates for Dry Powder Inhalation.

62. Johannes Raster (April 2019) – Visiting Pharmacy Student Intern, University of Greifswald, Diploma Title: Enhancing the Aqueous Dissolution Behavior of Curcumin and Ursolic Acid Utilizing Advanced Formulation Techniques.

63. Hannes Gierke (April 2018) – Visiting Pharmacy Student Intern, University of Greifswald, Diploma Title: Processability of Different Drug-Polymer Blends by Hot Melt Extrusion.

64. Laura Adam (April 2017) – Visiting Pharmacy Student Intern, University of Greifswald, Diploma Title: Extrudable Controlled-release Dosage Forms Containing Thermoplastic Polyurethane.

XII. Publications

1. R.O. Williams III and J.W. McGinity, The Use of Tableting Indices to Study the Compaction Properties of Powders, *Drug Development and Industrial Pharmacy*, 14(1988) 1823-1844.

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14. R. O. Williams III and V. Mahaguna, Preformulation studies on Freund's Incomplete Adjuvant Emulsion, *Drug Development and Industrial Pharmacy*, 24(1998) 157-162.

15. R. O. Williams III, M. Repka, and J. Liu, Influence of Propellant Composition on Drug Delivery From a Pressurized Metered-dose Inhaler, *Drug Development and Industrial Pharmacy*, 24(1998) 763-770.

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92. Release Mechanism of Alprazolam from Controlled Release Tablets Containing HPMC and Various Excipients. Proceedings of the American Association of Pharmaceutical Scientists Meeting, Toronto, Canada, November 2002.
93. Quantitation of Plasticizers from Cellulose Acetate Phthalate Films by High-Performance Liquid Chromatography (HPLC) – Separation. Proceedings of the American Association of Pharmaceutical Scientists Meeting, Toronto, Canada, November 2002.
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101. Micronized Powders of a Poorly Water Soluble Drug Produced by a Spray Freezing into Liquid Emulsion Process. Proceedings of the 30th Controlled Release Society Meeting, Glasgow, Scotland, July 2003.
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103. Physicochemical Properties of Itraconazole Produced by Spray-Freezing into Liquid Process. Proceedings of the First EUFEPS Conference, Versailles, France, October, 2003.
104. Stability of Amorphous Danazol Powders Produced by Spray Freezing Into Liquid Technology: Influence of Excipient Type and Glass Transition Temperature. Proceedings of the American Association of Pharmaceutical Scientists, Salt Lake City, UT, October 2003.
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106. The Stability of Protein Powder: Spray Freezing Into Liquid Versus Spray Freeze Drying. Proceedings of the American Association of Pharmaceutical Scientists, Salt Lake City, UT, October 2003.
107. The Influence of Process Parameters on the Stability of Protein Nanoparticles Produced by Spray Freezing Into Liquid. Proceedings of the American Association of Pharmaceutical Scientists, Salt Lake City, UT, October 2003.
108. Nebulization of a Suspension Containing Itraconazole Prepared by Evaporative Precipitation Into Aqueous Solution. Proceedings of the American Association of Pharmaceutical Scientists, Salt Lake City, UT, October 2003.
109. Spray Freezing Into Liquid of Itraconazole for Pulmonary Delivery. Proceedings of the American Association of Pharmaceutical Scientists, Salt Lake City, UT, October 2003.
110. High Potency Itraconazole with Enhanced Dissolution Rates Produced by Evaporative Precipitation Into Aqueous Solution. Proceedings of the American Association of Pharmaceutical Scientists, Salt Lake City, UT, October 2003.
111. Influence of Stabilizer Type on Dissolution Properties of Itraconazole Produced by Evaporative Precipitation Into Aqueous Solution. Proceedings of the American Association of Pharmaceutical Scientists, Salt Lake City, UT, October 2003.

112. Rapid Release High Potency Danazol Powders Produced by Spray Freezing Into Liquid (SFL) – Organic Solvent Process. Proceedings of the American Association of Pharmaceutical Scientists, Salt Lake City, UT, October 2003.
113. Controlling Particle Characteristics of Itraconazole Powders Produced by Spray-Freezing Into Liquid – Organic Solution Versus Emulsion Liquid Feed Solutions. Proceedings of the American Association of Pharmaceutical Scientists, Salt Lake City, UT, October 2003.
114. Evaporative Precipitation Into Aqueous Solution Process: Investigation of Processing Parameters to Enhance Dissolution of Danazol. Proceedings of the American Association of Pharmaceutical Scientists, Salt Lake City, UT, October 2003.
115. Stability and Delivery of Protein Powders Prepared by the Spray Freezing into Liquid Nitrogen Technology, Abstracts of Papers, 227th American Chemical Society Meeting, Anaheim, CA, March, 2004.
116. Comparison of Particle Formation Processes, Spray Freezing into Liquid and Evaporative Precipitation into Aqueous Solution: How Particle Formation Impacts Morphology and Performance, Proceedings of the 30th Controlled Release Society Meeting, Honolulu, HI, June, 2004.
117. Enhanced Solubility and Dissolution of Itraconazole Prepared by the Spray Freezing into Liquid Technique, Proceedings of the 30th Controlled Release Society Meeting, Honolulu, HI, June, 2004.
118. Stable Amorphous Danazol Nanostructured Powders Produced by Spray Freezing into Liquid Technology, Proceedings of the 30th Controlled Release Society Meeting, Honolulu, HI, June, 2004.
119. Homogenous Encapsulation of Protein Nanoparticles into Uniform Size Microspheres, Proceedings of the National Biotechnology Meeting, Boston, MA, June 2004.
120. Controlled Precipitation of Naproxen Nanoparticles, Proceedings of the American Institute of Chemical Engineers Meeting, Austin, TX, November, 2004.
121. Spray Freezing into Liquid Versus Spray Freeze Drying: The Influence of Atomization on Protein Aggregation and Biological Activity, Proceedings of the American Association of Pharmaceutical Scientists, Baltimore, MD, November, 2004.
122. Insulin Loaded Polymeric Microparticles: Formulation, Characterization, and Release Characteristics, Proceedings of the American Association of Pharmaceutical Scientists, Baltimore, MD, November, 2004.
123. The Use of Antioxidants to Stabilize Ethyl Lactate, Proceedings of the American Association of Pharmaceutical Scientists, Baltimore, MD, November, 2004.
124. Ultrarapid Freezing to Micronize Water Insoluble Drugs – A Comparison to Spray Freezing into Liquid, Proceedings of the American Association of Pharmaceutical Scientists, Baltimore, MD, November, 2004.
125. Design of a Restraint-Free Small Animal Dosing Chamber for Inhalation and Investigation of Drug Distribution Within the Chamber, Proceedings of the American Association of Pharmaceutical Scientists, Baltimore, MD, November, 2004.
126. Comparison of Powder Produced by Evaporative Precipitation into Aqueous Solution and Spray Freezing into Liquid, Proceedings of the American Association of Pharmaceutical Scientists, Baltimore, MD, November, 2004.

127. Rapid Release Tablet Formulation Containing Micronized Danazol Powder Produced by Spray Freezing into Liquid, Proceedings of the American Association of Pharmaceutical Scientists, Baltimore, MD, November, 2004.
128. Morphology of Poorly Water Soluble Drug Nanoparticles by a Cryogenic SEM Technique, Proceedings of the American Association of Pharmaceutical Scientists, Baltimore, MD, November, 2004.
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130. Influence of Processing on Stability of Insulin – Spray Freezing Into Liquid, Proceedings of the American Association of Pharmaceutical Scientists, Baltimore, MD, November, 2004.
131. Delivery of Poorly Water Soluble Drugs Using Nebulization, Proceedings of the15th Drug Delivery to the Lungs Conference, Aerosol Society, London, England, December, 2004.
132. Comparison of Commercial Itraconazole to Aerosolized Nanoparticle Itraconazole in a Murine Model for the Prevention of Invasive Pulmonary Aspergillus, Proceedings of Alcalde XIX Southwest Leadership Conference, Austin, Texas, April, 2005.
133. Novel Treatment of Pulmonary Aspergillosis Using Nebulized Itraconazole Nanoparticles in the Murine Model, Proceedings of the Respiratory Drug Delivery – Europe 2005 Conference, Paris, France, May, 2005.
134. Improved Dissolution Rate and Bioavailability Through the Formation of a Highly Miscible Binary Mixture, Proceedings of the Controlled Release Society Annual Meeting, Miami, FL, June, 2005.
    a. Paper awarded the Controlled Release Society's Innovative Aspects of Oral Drug Delivery and Absorption Graduate/Post-Doc Award
135. Rapid Release, High Potency Itraconazole Formed by Evaporative Precipitation Into Aqueous Solution, Proceedings of the Controlled Release Society Annual Meeting, Miami, FL, June, 2005.
    a. Paper nominated for the Controlled Release Society's Innovative Aspects of Oral Drug Delivery and Absorption Graduate/Post-Doc Award
136. Particle Engineering for Rapid Dissolution Rates of Poorly Water Soluble Drugs, Proceedings of the American Institute of Chemical Engineers 2005 Annual Meeting, Cincinnati, OH, October, 2005.
137. Cryogenic Liquids, Nanoparticles and Microencapsulation, Proceedings of the 15th Symposium on Microencapsulation, Parma, Italy, September, 2005.
    a. Invited Speaker
138. Improved Danazol Supersaturation and Oral Bioavailability via Formulation into an Amorphous Solid Solution, Proceedings of the American Association of Pharmaceutical Scientists Meeting, Nashville, TN, November, 2005.
139. Characterization of Nebulized Itraconazole Nanoparticles and Delivery to the Murine Lung, Proceedings of the American Association of Pharmaceutical Scientists Meeting, Nashville, TN, November, 2005.
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256. S. Thakkar, X. Li, R. o. Williams III and Z. Cui, A Method of Preparing Dry Powder Vaccines Adjuvanted with Aluminum Salts, Proceedings of the American Association of Pharmaceutical Scientists Meeting, San Diego, CA, November 2014.
257. J. Maincent, S. Huang, L. Najvar, W. Kirkpatrick, T. Patterson, N. Wiederhold, J. Peters and R. O. Williams III, Enteric Polymer and Hydrophilic Additive Processed by Hot-Melt Extrusion to Improve Bioavailability of Itraconazole, Proceedings of the American Association of Pharmaceutical Scientists Meeting, San Diego, CA, November 2014.
258. J. LaFontaine, L. Prasad, C. Brough, K. Ford, R. O. Williams III and J. W. McGinity, Processing and Characterization of PVP- and HPMC-Based Amorphous Solid Dispersions: A Comparison of Hot Melt Extrusion and KinetiSol® Dispersing, Proceedings of the American Association of Pharmaceutical Scientists Meeting, San Diego, CA, November 2014.
259. A. B. Watts, S. R. Carvalho, S. Liu, J. I. Peters and R. O. Williams III, Brittle Matrices as a DPI Platform for Combination Therapies, Proceedings of the Respiratory Drug Delivery Meeting, Nice, France, May 2015. (Chosen as "Posters on the Podium" special recognition).
260. J. Maincent, L. K. Najvar, W. R. Kirkpatrick, T. F. Patterson, N. P. Wiederhold, Jay I. Peters and R. O. Wililams III, Administration of a Melt Extruded Itraconazole Amorphous Solid Dispersion: Criticality of the Animal Model Selection, Proceedings of the 3rd International TB-Meeting, Inhaled Therapies for Tuberculosis and Other Infectious Diseases, Parma, Italy, October 2015.
261. J. Maincent, L. Prasad, J. S. LaFountaine, S. Hengsawas and R. O. Williams III, Extrudable Felodipine Solid Dispersions with Enteric Polymers, Proceedings of the American Association of Pharmaceutical Scientists Meeting, Orlando, FL, November 2015.
262. S. Thakkar, R. O. Williams III and Z. Cui, Stability of Aluminum Salt-Adjuvanted Vaccine Dry Powder, Proceedings of the American Association of Pharmaceutical Scientists Meeting, Orlando, FL, November 2015.

263. L. Prasad, J. S. LaFountaine, J. Maincent, J. M. Keen, R. O. Williams III, Electrostatic Powder Deposition to Manufacture Free Films for Drug Delivery, Proceedings of the American Association of Pharmaceutical Scientists Meeting, Orlando, FL, November 2015.
264. S. Hengsawas and R. O. Williams III, Degradation of Albendazole during Hot Melt Extrusion, Proceedings of the American Association of Pharmaceutical Scientists Meeting, Orlando, FL, November 2015.
265. J. S. LaFountaine, L. Prasad, C. Brough, D. Miller, D. Lubda, J. W. McGinity and R. O. Williams III, Processing and Characterization of Ritonavir-Polyvinyl Alcohol Amorphous Solid Dispersions by KinetiSol Dispersing, Proceedings of the American Association of Pharmaceutical Scientists Meeting, Orlando, FL, November 2015.
266. C. Moon, Y. Zhang, A. B. Watts and R. O. Williams III, Thin Film Freezing for Production of an Amorphous Mannitol/Lysozyme Formulation for Inhalation: A Comparison of Freezing Techniques, Proceedings of the Respiratory Drug Delivery Meeting, Phoenix, AZ, April 2016.
267. H. D. C. Smyth, L. A. Heersema, C. Moon, A. B. Watts and R. O. Williams III, Amorphous or Crystalline? Evaluating Particle Engineering Approaches for Inhalation Products, Proceedings of the Respiratory Drug Delivery Meeting, Goa, India, November 2016.
268. S. H. Surasarang, G. Florova, A. A. Komissarov, S. Shetty, S. Idell and R. O. Williams III, Optimization of Formulation for Novel Inhaled Anti-Idiopathic Pulmonary Fibrosis Therapeutics, Proceedings of the American Thoracic Society, November 2016.
269. J. S. LaFountaine, D. J. Ellenberger, D. A. Miller, L. K. Prasad, B. Sinko, E. Borbas, R. Lingamaneni, J. W. McGinity and R. O. Williams III, Mucoadhesive Amorphous Solid Dispersions, Proceedings of the American Association of Pharmaceutical Scientists Annual Meeting, Denver, CO, November 2016.
270. T. N. Tarbox, E. Seminerio, A. Rossi, F. Buttini, A. B. Watts, P. Colombo and R. O. Williams III, Preparation and Characterization of Spray-Dried Powders of Voriconazole and Calcium Phosphate Nanoparticles for Pulmonary Administration, Proceedings of the American Association of Pharmaceutical Scientists Annual Meeting, Denver, CO, November 2016.
271. Z. Warnken, D. Moraga-Espinoza, R. O. Williams III and H. D. C. Smyth, Shadow Motion Analysis: Analyzing *in vivo* Relevant Foam Stability by Image Analysis, Proceedings of the American Association of Pharmaceutical Scientists Annual Meeting, Denver, CO, November 2016.
272. J. Maincent, L. Adam and R. O. Williams III, Affinisol ™ HPMC Melt-extruded Matrix Tablet for Controlled Release of Soluble Drugs, Proceedings of the American Association of Pharmaceutical Scientists Annual Meeting, Denver, CO, November 2016.
273. C. Moon, Y. Zhang, A. B. Watts and R. O. Williams III, Stability of Freeze-thawed and Freeze-dried Lysozyme by Different Freezing Techniques, Proceedings of the American Association of Pharmaceutical Scientists Annual Meeting, Denver, CO, November 2016.
274. C. Moon, A. B. Watts and R. O. Williams III, Development of Aerosolized Voriconazole Formulations for Dry Powder Inhalation, Proceedings of the American Association of Pharmaceutical Scientists Annual Meeting, Denver, CO, November 2016.

275. S. Huang, K. P. O'Donnell, J. O'Brien, J. Stutzman, S. M. Delpon DeVaux and R. O. Williams III, Processing of a Thermally Labile Active Ingredient by Hot-melt Extrusion, Proceedings of the American Association of Pharmaceutical Scientists Annual Meeting, Denver, CO, November 2016.
276. S. Huang, A. Miller, F. Zhang and R. O. Williams III, Solvent-Assist Hot-melt Extrusion Technique Minimizes Thermal-labile Drug Degradation, Proceedings of the American Association of Pharmaceutical Scientists Annual Meeting, Denver, CO, November 2016.
277. C. Moon, A. B. Watts and R. O. Williams III, Novel Inhaled Voriconazole Formulation for Pulmonary Aspergillosis, Proceedings of the International Society of Aerosols in Medicine Meeting, Sante Fe, NM, June 2017.
278. S. Fukuda, P. Enkhbaatar, C. L. Nelson, S. Hengsawas, R. O. Williams III, A. A. Komissarov, G. Florova, K. P. Singh, T. H. Shaffer, M. R. Wolfson and S. Idell, Comparison of Nebulized Plasminogen Activators for Management of Inhalational Smoke Induced Acute Lung Injury in Sheep: Impact on Physiological Profile, Proceddings of the American Thoracic Society, May 2018. (submitted)
279. C. Moon, A. B. Watts and R. O. Williams III, Dissolution Tests for Voriconazole Powders Intended for Dry Powder Inhalation, Proceedings of the American Association of Pharmaceutical Scientists Meeting, San Diego, CA, November 2017.
280. Z. Warnken, H. D. C. Smyth and R. O. Williams III, 3D Printed Nasal Casts for Analyzing the Effect of Personalized Administration Angles on the Targeting of Nasal Spray Deposition in Pediatrics and Adults, Proceedings of the American Association of Pharmaceutical Scientists Meeting, San Diego, CA, November 2017.
281. S. Sahakijpijarn, A. A. Komissarov, G. Florova, S. Shetty, S. Idell and R. O. Williams III, Development of CSP7 Nebulized Peptide Treatment for Idiopathic Pulmonary Fibrosis, Proceedings of the American Association of Pharmaceutical Scientists Meeting, San Diego, CA, November 2017.
282. H. Takabe, Z. Warnken, D. Davis and R. O. Williams III, Atovaquone Amorphous Solid Dispersions Improved by Combining SEDDS and Hot Melt Extrusion, Proceedings of the American Association of Pharmaceutical Scientists Meeting, San Diego, CA, November 2017.
283. M. Hanada, S. V. Jermain and R. O. Williams III, Assessment of Extrudability of Amorphous Solid Dispersions Containing Insoluble Carriers in a Ternary Mixture with Drug and Polymer, Proceedings of the American Association of Pharmaceutical Scientists Meeting, San Diego, CA, November 2017.
284. X. Ma, S. Huang and R. O. Williams III, Influence of Energy Input Type on the Physical Stability of Nifedipine Amorphous Solid Dispersion Prepared by Hot Melt Extrusion, Proceedings of the American Association of Pharmaceutical Scientists Meeting, San Diego, CA, November 2017.
285. S. V. Jermain, S. A. Thompson and R. O. Williams III, Necessity of Evaluating Drug Stability During Pre-Formulation Assessment When Preparing Amorphous Solid Dispersions, Proceedings of the 11th World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Granada Spain, March 19-22, 2018.
286. G. Florova, K. Koenig, K. Sarva, P. Enkhbatar, S. Fukuda, C. Nelson, M. R. Wolfson, T. H. Shaffer, R. O. Williams III, S. H. Surasarang, S. Sahakijpijarn, S. Idell and A. A. Komissarov, Delivery Matters: A Biochemical Analysis of the Effects of

Nebulized Plasminogen Activators on Smoke Induced Acute Lung Injury in Sheep, Proceedings of the American Thoracic Society Annual Meeting, San Diego, CA, May 18-23, 2018. (ATS A7222/P1306)

287. Y. Zhang, J. J. Koleng, A. B. Watts and R. O. Williams III, Excipient Free Dry Powder for Inhalation of Caveolin-1 Scaffolding Domain Peptide, Proceedings of the American Association of Pharmaceutical Scientists Meeting, Washington DC, November 2018.
288. C. Moon, A. B. Watts and R. O. Williams III, Development of Surface-modified High Potency Nanoaggregates of Voriconazole Powders for Dry Powder Inhalation, Proceedings of the American Association of Pharmaceutical Scientists Meeting, Washington DC, November 2018.
289. U. Gala, D. A. Miller and R. O. Williams III, Enhancing Bioavailability of Abiraterone Through Use of KinetiSol Technology, Proceedings of the American Association of Pharmaceutical Scientists Meeting, Washington DC, November 2018.
290. S. Sahakijpijarn, S. H. Surasarang, G. Florova, A. A. Komissarov, C. L. Nelson, P. Erkhbaatar, S. Fukuda, Mr. R. Wolfson, T. H. Shaffer, S. Idell and R. O. Williams III, Effects of Lyophilization and Nebulization on Activity and Stability of Single-Chain Tissue-Type and Single-Chain Urokinase Plasminogen Activator for Treatment of Inhalational Smoke-Induced Acute Lung Injury, Proceedings of the American Association of Pharmaceutical Scientists Meeting, Washington DC, November 2018.
291. M. Hanada, S. V. Jermain, X. Lu, Y. Su and R. O. Williams III, Predicting Stability of Ternary Amorphous Solid Dispersion Using Specific Mechanical Energy Input from Hot Melt Extrusion, Proceedings of the American Association of Pharmaceutical Scientists Meeting, Washington DC, November 2018.
292. X. Ma, S. Huang, M. Lowinger, X. Liu and R. O. Williams III, Influence of Mechanical and Thermal Energies on Nifedipine Amorphous Solid Dispersion Prepared by Hot Melt Extrusion. Proceedings of the American Association of Pharmaceutical Scientists Meeting, Washington DC, November 2018.
293. S. V. Jermain, D. A. Miller and R. O. Williams III, KinetiSol Dispersing Enables Homogeneous Dispersion of Amorphous API in a Polymeric Carrier, Proceedings of the American Association of Pharmaceutical Scientists Meeting, Washington DC, November 2018.
294. Z. Warnken, D. Davis, H. Takabe, Y. Zhang and R. O. Williams III Repurposing Atovaquone for Glioblastoma Multiforme Treatment by Combining a Spontaneously Emulsifying Component with a Hot Melt Extruded Solid Dispersion, Proceedings of the American Association of Pharmaceutical Scientists Meeting, Washington DC, November 2018.

295. XIV. Invited Talks

1. Proprietes de Compaction de Poudres, Servier Laboratories, Orleans, France, June, 1985.

2. A Study of the Influence of Magnesium Stearate or Talc on the Compaction Properties of Aspirin and Sodium Sulfathiazole Using Tableting Indices, Proceedings of the Fourth International Conference on Pharmaceutical Technology, Paris, France, June, 1986.

3. Tableting - An Industrial Viewpoint, Pharmaceutics Series, University of Cincinnati, Cincinnati, OH, October, 1990.

4. Utilization of Sodium Chloride, Fructose, and Urea to Modify the Surface Tension of RG-12915A Solutions, The University of Texas at Austin, Austin, TX, September, 1991.

5. Tableting Indices in Compaction Studies, Proc. Midwest Regional Meeting, American Association of Pharmaceutical Scientists, Chicago, IL, May, 1992.

6. Theory and Practical Applications of Tableting Indices in Compaction Studies, Proc. Fifth Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Las Vegas, NV, November, 1990.
    a. Invited Speaker

7. Current Issues and Trends in Technology Transfer, Sixth International Congress for Pharmaceutical Engineering, International Society for Pharmaceutical Engineering, Philadelphia, PA, May, 1994.
    a. Invited Speaker

8. Simulated Food Effects on Drug Release from Film Coated Pellets, Proceedings of the 15th Pharmaceutical Technology Conference, Oxford, England, March, 1996.

9. Optimization of Metered-Dose Inhaler Suspension Formulations, Fachbereich Pharmazie, Freie Universitat Berlin, Berlin, Germany, March, 1996.

10. Formulation and Stability of a Three Component Suspension, Horizon Pharmaceuticals, Louisville, KY, May, 1996.

11. Optimization of a Matrix Tablet Formulation Containing Nonoxynol-9 Using Cellulose Ethers, The Dow Chemical Company, Cellulosics Division, Midland, MI, November, 1997.

12. Delivering Steroids to the Nose Using an Aqueous Based Pump System, Honduran Medical Association, Tegucigalpa, Honduras, Central America, October, 1998.
    a. Invited Plenary Speaker

13. Preparation of Chitosan Microspheres for Nasal and Pulmonary Release of Therapeutic Macromolecules, Proceedings of the Association of Pharmaceutical Technology Professors of Spain, Santiago, Spain, February, 1999.

14. The Effect of Co-Grinding Drug and a Polymeric Surfactant on a Model pMDI Suspension, Proceedings of the 18th Pharmaceutical Technology Conference, Utrecht, The Netherlands, April, 1999.
    a. Invited Speaker

15. Buccal Delivery of Insulin Via Aerosol Spray, Proceedings of the Third World Meeting On Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Berlin, Germany, April, 2000.
    a. Session Chair – Scientific Program

16. Introduction to Pharmaceutical Development and Technology, Invited Short Course, International Society of Pharmaceutical Engineers, Philadelphia, PA, May, 2001.
    a. Invited Speaker

17. Utilization of a Novel Cryogenic Spray-freezing Into Liquid (SFL) Process to Encapsulate Danazol, Proceedings of the 13th International Symposium on Microencapsulation, Angers, France, September, 2001.
    a. Session Chair – Scientific Program

18. Austin's Road to Bio: Where We Are and Where We're Going – Drug Delivery and Nanotechnology. Austin Chamber of Commerce, Austin, TX, January, 2003.
    a. Invited Expert Panel – Speaker

19. Improvement of Dissolution Rates of Poorly Water Soluble Drugs Using A New Particle Engineering Technology – Spray Freezing into Liquid. Proceedings of the American Chemical Society, Polymeric Drug Delivery: Science and Application, New York, NY, September, 2003.
    a. Invited Speaker
    b. Session Chair – Engineered Drug Particles

20. Enabling Technologies Helping to Expand Drug Delivery in the Pharmaceutical Industry: Nanotechnology. International Conference on Drug Development, Austin, Texas, February, 2004.
    a. Invited Speaker

21. Novel Processes to Enhance Dissolution and Bioavailability of Poorly Water Soluble Drugs, Barnett International Conference on Strategies for Improving Solubility, Philadelphia, PA, June 2004.
    a. Invited Speaker

22. Recent Advances in Particle Engineering Processes – Precipitation and Freezing, Short Course, Advances in Controlled Release and Drug Delivery Technologies, The Center for Microencapsulation & Drug Delivery, College Station, TX, October 2004.
    a. Invited Speaker

23. Solid Dispersions and Nanotechnology Systems for Poorly Water Soluble Drugs, Second Annual Anthony P. Simonelli Conference in Pharmaceutical Sciences, Long Island University, New York, NY, June, 2005.
    a. Invited Speaker

24. Cryogenic Liquids, Nanoparticles and Microencapsulation, 15th International Symposium on Microencapsulation, Parma, Italy, September 2005.
    a. Invited Lecture

25. Nanoparticles for Pharmaceutical Applications, DPT Laboratories, LTD., San Antonio, TX, October 2005.
    a. Invited Lecture

26. Texas Life Sciences: More Than Just Your Medicine Cabinet, Proceedings of the Bio Texas Summit 06 Meeting, Austin, TX, February, 2006.
    a. Invited Lecture and Panelist

27. Enabling Technologies Helping to Expand Drug Delivery in the Pharmaceutical Industry: Nanotechnology, Committee of Emerging Technology and Telecommunications, City of Austin, Austin, TX, July 2006.
    a. Invited Lecture

28. Manufacturing Challenges for Production of Nanoparticles. Proceedings of the World Congress of Pharmacy and Pharmaceutical Sciences 2006, 66th International Congress of FIP, Salvatore, Brazil, August 2006.
    a. Invited Lecture

29. An Alternative Route of Delivery for Antifungal Drugs to Treat Fungal Infections – Pulmonary Drug Delivery. Asuragen Inc., Austin, TX, January 2007.
    a. Invited Lecture

30. Positioning Investors for the Nest Wave in Pain Management, Fentanyl Taifun – Inhaled Fentanyl for Breakthrough Pain, Oppenheimer Healthcare, New York City, NY, March, 2007.
    a. Invited Lecture

31. Advances in Pulmonary Drug Delivery – Inhaled Nanoparticles, Distinguished Faculty Seminar, Celebrating Research Achievements, University of Texas at Austin, College of Pharmacy, Austin, Texas, April, 2007.
    a. Invited Lecture

32. Pharmaceutical Development in a Collaborative Setting: A Successful Formula, Proceedings of the International Biotechnology Congress and Exhibition: BioMonterrey 08, Monterrey, Mexico, October 2008.
    a. Invited Lecture

33. Pulmonary Delivery of Itraconazole Nanoparticles to Treat Life Threatening Fungal Infections, School of Pharmacy, University of Kansas, Lawrence, KS, April 2009.
    a. Invited Lecture

34. Formulation and Characterization of Itraconazole Nanoparticles Made by Advanced Evaporative Precipitation Into Aqueous Solution, Proceedings of Particles 2010, Orlando, FL, May, 2010.
    a. Invited Lecture

35. Novel Plasma Deposited Stability Enhancement Coating for Amorphous Ketoprofen, Proceedings of the 240th American Chemical Society Meeting (Polymeric Materials: Science and Engineering), Boston, MA, August, 2010.
    a. Invited Lecture – Stephanie Bosselmann

36. Novel Particle Engineering Technologies for Enhancing Bioavailability, February, 2010
    a. Merck & Company, Kenilworth, NJ
    b. Hoffmann LaRoche, Nutley, NJ
    c. Columbia Laboratories, Inc., Livingston, NJ
    d. ThePharmaNetwork, West Orange, NJ

37. Steps to Getting Published in a Research Journal, Proceedings of the American Association of Pharmaceutical Scientists Meeting, San Diego, CA, November, 2014.

38. J. Maincent, J. I. Peters and R. O. Williams III, Evolution of Inhaled Antifungals for Targeted Lung Delivery, Proceedings of the 3rd International TB-Meeting, Inhaled Therapies for Tuberculosis and Other Infectious Diseases, Parma, Italy, October, 2015. (invited talk)

39. R. O. Williams III, Closing the Gap Between Academia and Life Science Community, Austin Technology Council, Life Sciences Summit 2015, Austin, TX, October, 2015. (invited talk)

40. R. O. Williams III, Responding to Manuscript Reviews, Steps to Getting Published in a Research Journal, Proceedings of the American Association of Pharmaceutical Scientists Meeting, Orlando, FL, November 2015.

41. R. O. Williams III, Responding to Manuscript Reviews, Manuscript Review: Writing, Receiving and Responding, Proceedings of the American Association of Pharmaceutical Scientists Meeting, Orlando, FL, November 2015.

42. R. O. Williams III, Thermal Processing for Drug Delivery, University of Chile, Santiago, Chile, August 2016.

43. R. O. Williams III, How to Publish and Review in the Pharmaceutical Sciences, University of Chile, Santiago, Chile, August 2016.

44. R. O. Williams III, Thermal Processing Enhances Oral Drug Delivery, International Pharmaceutical Technology Conference 2016, The Engineering and Physical Sciences Research Council, EHDA Network, Leicester, United Kingdom, November 4, 2016.

45. R. O. Williams III, Development of Poorly Water-Soluble Drugs – A Technology Timeline, University of Houston, College of Pharmacy, October 12, 2017.

46. R. O. Williams III, Kinetisol Overview, Proceedings of the American Association of Pharmaceutical Scientists Meeting, San Diego, CA, November 2017.

47. R. O. Williams III, 5-Ways to Not Get Published: Following Instructions and Improving Your Writing Skills, Proceedings of the American Association of Pharmaceutical Scientists Meeting, San Diego, CA, November 2017.

48. R. O. Williams III, Technologies to Enhance Delivery of Poorly Water Soluble Drugs, Proceedings of the 11th World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Granada Spain, March 19-22, 2018. (Invited Plenary Speaker)

49. S. V. Jermain, D. J. Ellenberger and R. O. Williams III, KinetiSol Dispersing Improves In Vitro and In Vivo Dissolution of Vemurafenib, Proceedings of the 11th World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Granada Spain, March 19-22, 2018.

50. R. O. Williams III, Formulating Poorly Water Soluble Drugs – Importance of Process Selection, Proceedings of the American Association of Pharmaceutical Scientists Meeting, Washington DC, November 2018. (invited plenary talk).

51. R. O. Williams III, Formulating Poorly Water Soluble Drugs – Choosing the Right Process, Proceedings of the 12th Chinese Pharmaceutical Conference 2018, Guangzhou, China, November 2018 (invited plenary talk).

XV. Book Reviews

1. R. O. Williams III. Solubility and Solubilization in Aqueous Media. By Samuel H. Yalkowsky (University of Arizona). Oxford University Press: New York. 1999. xvi + 464 pp., J. Am. Chem. Soc. (2000), 122(40) 9882.

XVI. Invited Book Chapters and Books

1. V. Mahaguna, R. O. Williams III and T. C. Hardin, Trends in Antifungal Research. In P. Jolles (ed.), *New Approaches to Drug Development*, Birkhauser Publishers, Boston, (2000) 55-68.

2. R. O. Williams III and V. Mahaguna, Coatings. In A. Gennar (ed.), *FMC Problem Solver and Reference Manual*, Published by FMC Corporation, Princeton, 2000.

3. J. M. Vaughn and R. O. Williams III, Pharmaceutical Calculations and Compounding. In D. Ginsberg (ed.), *ASHP's PharmPrep, Second Edition*. Published by the American Society of Health-System Pharmacists, Bethesda, MD, 2003.

4. K. A. Overhoff, K. P. Johnston and R. O. Williams III, Improvement of Dissolution Rate of Poorly Water Soluble Drugs Using a New Particle Engineering Process – Spray Freezing Into Liquid. In S. Svenson (ed.), *Polymeric Drug Delivery Volume II – Polymeric Matrices and Drug Particle Engineering*, Published by ACS Symposium Series, Vol. 924, American Chemical Society, Washington, D.C., 2005.

5. K. A. Overhoff, A. Moreno, D. A. Miller, K. P. Johnston and R. O. Williams III, Advances in Drug Delivery Technologies for Nanoparticulates. In J. Zach Hilt, J. Brock Thomas and N. A. Peppas (eds.), *Nanotechnology in Therapeutics: Current Technology and Applications*, Published by Horizon Scientific Press, Norwich, United Kingdom, 2007.

6. J. M. Vaughn, K. R. Vaughn and R. O. Williams III, Pharmaceutical Calculations and Compounding. In D. Ginsberg (ed.), *ASHP's PharmPrep, Third Edition*. Bethesda: American Society of Health-System Pharmacists, Bethesda, 2007. Online version: updated annually, 2007, 2008, 2009. www.pharmpreponline.com.

7. J. M. Vaughn, K. P. O'Donnell and R. O. Williams III, Pharmaceutical Calculations and Compounding. In D. Ginsberg (ed.), *ASHP's PharmPrep, Fourth Edition*. Bethesda: American Society of Health-System Pharmacists, Bethesda. Online version: updated 2010. www.pharmpreponline.com.

8. J. M. Vaughn and R. O. Williams III, Nanoparticle Engineering. In J. Swarbrick (ed.), *Encyclopedia of Pharmaceutical Technology, Third Edition*. Published by Marcel Dekker Inc., New York, NY, 2006, 2384-2398.

9. P. Sinswat and R. O. Williams III, Recent Advances in Nanoparticle-Based Drug Delivery Technologies and Their Applications for Particulate Drug Delivery Systems, MNV Ravi Kumar (ed.), *Handbook of Particulate Drug Delivery*. Published by American Scientific Publishers, Inc., Stevenson Ranch, CA, 2006.

10. R. O. Williams III and J. N. Brown, Dissolution of Modified-Release Oral Dosage Forms, V. Gray (ed.), *Dissolution Theory, Methodology and Testing.* Published by Dissolution Technologies, Inc., Hockessin, DE, 2007.

11. J. M. Vaughn, K. R. Vaughn and R. O. Williams III, Pharmaceutical Calculations and Compounding. In D. Ginsberg (ed.), *ASHP's PharmPrep, Online Edition*. Published by the American Society of Health-System Pharmacists, Bethesda, MD, 2008.

12. T. Purvis, K. A. Overhoff, P. Sinswat and R. O. Williams III, Immunosuppressant Drugs, R. O. Williams II, D. R. Taft and J. T. McConville (eds.), *Advanced Drug Formulation Design to Optimize Therapeutic Outcomes*. Published by Informa Healthcare, New York City, NY, 2008.

13. D. A. Miller, J. W. McGinity and R. O. Williams III, Solid Dispersion Technologies, R. O. Williams II, D. R. Taft and J. T. McConville (eds.), *Advanced Drug Formulation Design to Optimize Therapeutic Outcomes*. Published by Informa Healthcare, New York City, NY, 2008.

14. R. O. Williams III, D. R. Taft and J. T. McConville, *Advanced Drug Formulation Design to Optimize Therapeutic Outcomes*. In Drugs and the Pharmaceutical Sciences v. 172 series. ISBN-13: 978-1-4200-4387-7. 510 pages. Published by Informa Healthcare, New York City, NY, 2008.

15. N. A. Beinborn and R. O. Williams III, Polymeric Biomaterials in Pulmonary Drug Delivery. S. Dumitriu (ed.) In *Polymeric Biomaterials, Third Edition, Volume II, Medicinal and Pharmaceutical Applications of Polymers*. Published by CRC Press/Taylor & Francis Group, Inc., 2012 (invited).

16. A. B. Watts and R. O. Williams III, Formulation and Production Strategies for Enhancing Bioavailability of Poorly Absorbed Drugs. M. C. Rogge and D. R. Taft (eds.) In *Preclinical Drug Development, Second Edition*. Published by Informa Healthcare, New York City, NY, 2009 (invited).

17. A. B. Watts and R. O. Williams III, Nanoparticles for Pulmonary Delivery, H. Smyth and A. Hickey (eds.) In *Advances in Delivery Science and Technology Series: Controlled Pulmonary Drug Delivery*. Published by Springer Publishing, New York, NY, 2011 (invited).

18. B. Lang, J. M. Vaughn and R. O. Williams III, Nanoparticle Engineering in J. Swarbrick (ed.), *Encyclopedia of Pharmaceutical Technology, Fourth Edition*. Published by Marcel Dekker Inc., New York, NY, 2011 (in press, 2011)(invited).

19. Y. Wang and R. O. Williams III, Powders in L. V. Allen (ed.), *Remington: The Science and Practice of Pharmacy, 22nd Edition* by Pharmaceutical Press, London, England (invited).

20. H. Lirola and R. O. Williams III, Respiratory Drugs in L. V. Allen (ed.), *Remington: The Science and Practice of Pharmacy, 22nd Edition* by Pharmaceutical Press, London, England (invited).

21. R. O. Williams III, A. B. Watts and D. A. Miller, *Formulating Poorly Water Soluble Drugs*, in AAPS Advances in the Pharmaceutical Sciences Series, Vol. 3. ISBN 978-1-4614-1143-7. 731 pages, 187 illus., 52 in color. Published by Springer and AAPS Press, New York City, NY, 2012, eCite: http://dx.doi.org/10.1007/978-1-4614-1144-4. (Ranked one of top 50% most downloaded eBooks from Springer with 7,577 total chapter downloads between 2011-2013).

22. K. P. O'Donnell, D. A. Miller and R. O. Williams III, Preformulation and Analytical Characterization Relevant to Poorly Water Soluble Drugs in R. O. Williams III, A. B. Watts and D. A. Miller (eds.), *Formulating Poorly Water Soluble Drugs,* AAPS Advances in the Pharmaceutical Sciences Series 3, DOI 10.1004/978-1-4614-1144-4_2, American Association of Pharmaceutical Scientists, New York City, NY, 2012. (Ranked one of top 50% most downloaded eBooks from Springer with 7,577 total chapter downloads between 2011-2013).

23. S. Bosselmann and R. O. Williams III, Route Specific Challenges for Delivery of Poorly Water Soluble Drugs in R. O. Williams III, A. B. Watts and D. A. Miller (eds.), *Formulating Poorly Water Soluble Drugs*, AAPS Advances in the Pharmaceutical Sciences Series 3, DOI 10.1004/978-1-4614-1144-4_1, American Association of Pharmaceutical Scientists, New York City, NY, 2012. (Ranked one of top 50% most downloaded eBooks from Springer with 7,577 total chapter downloads between 2011-2013).

24. J. R. Hughey and R. O. Williams III, Solid-State Techniques for Improving Solubility in R. O. Williams III, A. B. Watts and D. A. Miller (eds.), *Formulating Poorly Water Soluble Drugs*, AAPS Advances in the Pharmaceutical Sciences Series 3, DOI 10.1004/978-1-4614-1144-4_3, American Association of Pharmaceutical Scientists, New York City, NY, 2012. (Ranked one of top 50% most downloaded eBooks from Springer with 7,577 total chapter downloads between 2011-2013).

25. W. Yang, D. E. Owens III and R. O. Williams III, Pharmaceutical Cryogenic Technologies in R. O. Williams III, A. B. Watts and D. A. Miller (eds.), *Formulating Poorly Water Soluble Drugs,* AAPS Advances in the Pharmaceutical Sciences Series 3, DOI 10.1004/978-1-4614-1144-4_11, American Association of Pharmaceutical

Scientists, New York City, NY, 2012. (Ranked one of top 50% most downloaded eBooks from Springer with 7,577 total chapter downloads between 2011-2013).

26. H. L. Dugas and R. O. Williams III, Nanotechnology for Pulmonary and Nasal Drug Delivery, J. L. Arias (ed.) in *Nanotechnology and Drug Delivery*, Science Publishers/CRC Press, Taylor and Francis Group, New York City, NY, 2014. (invited)

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30. D. Ellenberger, K. P. O'Donnell and R. O. Williams III, Optimizing the Formulation of Poorly Water-Soluble Drugs in R. O. Williams III, A. B. Watts and D. A. Miller, *Formulating Poorly Water Soluble Drugs (Second Edition)*, in AAPS Advances in the Pharmaceutical Sciences Series, Vol. 22. ISBN 978-3-319-420607-5 (ISBN 978-3-31-42609-9 eBook). 779 pages. Published by Springer and AAPS Press, New York City, NY, 2012, eCite DOI: 10.1007/978-3-319-42609-9_2.

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XVII. Patents (updated list provided on request; does not include foreign patent filings)

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41. E. Van Oort, B. Hoxha, A. K. Vajargah, R. O. Williams III, H. D. C. Smyth and S. Ferrati, Methods for Increasing Wellbore Strength (Provisional Patent Application 62/334,002 filed May 10, 2016; 16/300,123 filed November 9, 2018; PCT/US2017/031885 filed May 10, 2017) (6736 VAN).

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43. R. O. Williams III, H. Takabe, D. A. Davis and Z. Warnken, Compositions for the Improved Delivery of Drugs, UTSB.P1175US.P1 filed on September 11, 2017; PCT/US2018/050319 filed September 11, 2018; WO 2019/051437 published on March 14, 2019 (7174 WIL).

44. R. O. Williams III, M. Hanada and S. V. Jermain, Drug Compositions Containing Porous Carriers Made by Thermal or Fusion-Based Processes, USSN 62/556,954, UTSB.P1176US.P1 filed on September 11, 2017; PCT/US2018/050323 filed September 11, 2018 (7181 WIL).

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XVII. Professional Courses Offered

1. Robert O. Williams III and Scott V. Jermain, Overview and Selection of Solubilization Techniques, in Formulation Strategies for Oral Delivery of Poorly Soluble Drugs, AAPS eCourse, American Association of Pharmaceutical Scientists, May, 2017.

EXHIBIT B

Robert O. (Bill) Williams III, Ph.D.
Testimony by Deposition and/or Trial
2015-2019 (as of April 2019)

Notation:

D – Deposition(s)
Trial or Hearing

Leydig, Voit & Mayer, Ltd.
Ms. Brenda L. Danek
On behalf of Horizon US and Jagotec v. Watson Laboratories Inc. et al, (C.A. 2:13-cv-05124)
2014-2015 (case settled)
Consultant
E, D

Williams & Connolly LLP
Ms. Martha Kidd
On behalf of Pfizer Inc. v. Fresenius Kabi USA, LLC (Tygacil ANDA Litigation) C.A. No. 13-1893 (SLR) (SRF)
2013-2015 (case settled)
Consultant
D, Trial

Baker Botts
Mr. Stephen Hash
On behalf of Horizon, AstraZeneca and Pozen
Dr. Reddy's (CA 110cv-02317-JAP-DEA)
Lupin (CA 11-cv-04275-JAP-DEA)
Actavis (CA 3:130cv-03038-JAP-DEA)
Mylan (CA 3:13-cv-04022-JAP-DEA)
2014-2017 (case concluded)
Consultant
D, Trial

Finnegan, Henderson, Farabow, Garrett & Dunner, LLP
Mr. Justin Hasford
On behalf of Senju Pharmaceutical Co., LTE., Bausch & Lomb Inc, Bausch & Lomb Pharma Holdings Corp., vs. Lupin, Innopharma Licensing and Mylan Pharmaceuticals (14-cv-0067-JBS-KMW; 14:cv-04149-JBS-KMW; 14-cv-15144-

JBS-KMW; 15-cv-00335-JBS-KMW; 14-cv-06893-JBS-KMW and 15-cv-03240-JBS-KMW)
2015-2016 (case concluded)
Consultant
D, Hearing, Trial

Finnegan, Henderson, Farabow, Garrett & Dunner, LLP
Mr. Justin Hasford
On behalf of Valeant vs. Actavis and Taro (US 8,288,434; Onexton) (C. A. No. 2:16-cv-01105-SRC-CLW and 2:16-cv-00217-SRC-CLW)
2016-present
Consultant
D

Fitzpatrick, Cela, Harper & Scinto
James Tyminski
On behalf of Sanofi (for Multaq (dronedarone) product) vs. Glenmark Generics Inc. USA et al. - No. 14-cv-00264-RGA
2015-2016 (case settled)
Consultant
D

Bartlit Beck Herman Palenchar & Scott LLP
Mr. Nevin Gewertz
On behalf of Endo Pharmacueticals and Bayer IP vs. Paddock laboratories and Perrigo Company (Case No. 1:14-cv-01422)
2015-2016 (Case concluded)
Consultant
D, Trial

Finnegan, Henderson, Farabow, Garrett & Dunner, LLP
Mr. Justin Hasford
On behalf of Valeant Pharmaceuticals, Salix Pharmaceuticals, Progenics Pharmaceuticals and Wyeth vs. Mylan Pharmaceuticals (C.A. No. 2:15-cv-08180-SRC-CLW) (Relistor)
2016 - present
Consultant
D

Finnegan, Henderson, Farabow, Garrett & Dunner, LLP
Mr. Justin Hasford
On behalf of Valeant Pharmaceuticals, Salix Pharmaceuticals, Progenics Pharmaceuticals and Wyeth vs. Actavis Laboratories FL., Inc. (C.A. No. 2:16-cv-9038 (SRC)(CLW)) (Relistor)
2016 - present
Consultant
D, Trial

Williams & Connolly LLP
Ms. Martha Kidd
On behalf of Pfizer Inc. v. Mylan (Tygacil ANDA Litigation) C.A. No. 15-26 (SLR)
2016 (case settled)
Consultant
D, Trial

Fitzpatrick, Cella, Harper & Scinto
Mr. Joshua I. Rothman
On behalf of Amgen Inc. (issues relating to Sensipar ® (Cincalcet))
Amgen Inc, v. Aurobindo Pharma Ltd. Et al (C. A. No. 16-853 (GMS) Consolidated
2016 - present
Consultant
D

Finnegan, Henderson, Farabow, Garrett & Dunner, LLP
Mr. Justin Hasford
On behalf of Valeant Pharmaceuticals, Actavis (C.A. No. 2:16-cv-04344-JLL-JAD) (Carac)
2017-2018 (case settled)
Consultant
D

Exhibit C
Materials Considered

Rothman Decl. Exhibit	Document
1	U.S. PAT. NO. 9,375,405 ("the '405 patent")
2	PHARMACEUTICS: THE SCIENCE OF DOSAGE FORM DESIGN, 366-368, 406-408, Michael E. Aulton ed. (2nd ed. 2002) ("Aulton").
3	HANDBOOK OF PHARMACEUTICAL EXCIPIENTS, Raymond C. Rowe et al. eds., 118-121, 129-133, 317-322, 326-329, 581-585. 691-694 (6th ed. 2009) ("Handbook of Pharmaceutical Excipients").
4	REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY, Alfonso R. Gennaro ed., 1032 (20th ed. 2000)("Remington").

CERTIFICATE OF SERVICE

I hereby certify that on June 28, 2019, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on June 28, 2019, upon the following in the manner indicated:

Benjamin J. Schladweiler, Esquire — *VIA ELECTRONIC MAIL*
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Jack B. Blumenfeld (#1014)